

Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Claim 1 has been amended to incorporate the subject matter of claim 3, which has been canceled, and the dependencies of other dependent claims have been amended accordingly. Claim 19 has been amended in a manner similar to claim 1.

Claim Rejections - 35 USC § 102 and § 103

Claims 1, which has been amended to include subject matter previously presented in dependent claim 3, recites a method for registering an image data set for visualizing internal areas of the body that includes, *inter alia*, determining a relative position of an imaging device and an external body part, producing an image data set for the internal area using the imaging device and not including data on the external body part, and registering the data set of the internal area based on the relative position between the imaging device and the external body part. The relative position of the imaging device and external body part is determined by providing the external body part with markers, moving the imaging device from an initial position into one or more positions in which the markings appear in a defined position with respect to one another and recording the movement of the imaging device.

Similarly, claim 19 has been amended to recite a method for registering an image data set for visualizing an internal area of the body that includes, *inter alia*, receiving data indicative of the relative position between an imaging device and an external body part, wherein the data includes data representative of the imaging device being in an initial position and one or more positions in which markers disposed on the external body part appear in a defined position with respect to each other. The method further includes receiving data indicative of an image data set for the internal area of the body being obtained from the imaging device and not including data on the external body part.

The claimed invention deals with a method that allows for registration of image data in which the data set only comprises an internal area of the body or only parts of the anatomy, e.g., only vessels. One problem with registration of this type of image data is that these internal areas of the body often do not comprise any natural

landmarks, e.g., in a patient's brain, and also cannot easily be provided with artificial landmarks. The claimed method allows for registration of image data in which the data set comprises an internal area of the body. Using relative positional information, e.g., angles, and perspective registration, the claimed invention allows a volume data set to be aligned without points of the surface of the patient having to be contained in the image data set.

In rejecting claims 1-19 as being anticipated by Cosman, the Office Action provides the following discussion.

Cosman discloses a system and method for stereotactic registration of image scan data including determining a positional relationship of the probe 1 to the head H by combining position data on the probe 1 with data from some imaging means such as CT, MRI, or X-ray scanners showing internal views (col 4, lines 43-55). Cameras 4,5 are directed at a field including the patient's head H and the probe 1. The orientation and quantification of the camera coordinate data taken from the scan images in the cameras is registered by index spots 8A-C placed on the patient's head. Alternatively, these index spots may be a head ring which is fixed firmly on the patient's skull. When the index spots are in view of the cameras, the appropriate transformations are made by the processor DP based on the coordinates of the index markers which are known beforehand to the entire dataset (CT or MRI) of anatomy in the memory M. Thus, the reference points are used to relate objects in the camera fields of view to data for combination with the stored anatomical data (col 5, lines 46-62). Additionally, the probe carries two index markers as light sources 2, 3, wherein the cameras sense the orientation of such markers and thus of probe 1. Therefore, the physical position of the probe 1 relative to the interior CT or MRI data is also known. Since light sources 2, 3 are in a predetermined orientation relative to a tip 9 of the probe 1 (defined by object data), the actual physical location of the tip 9 relative to the anatomy may be computed in the processor DP (col 5, line 63-col 6, line 7).

It is unclear how the Examiner is applying Cosman to each of the 19 claims purportedly anticipated by Cosman in that many of the elements recited in claim 1 and claim 3 (and various other dependent claims) are not addressed in the rejection. For at least this reason, the rejection should be withdrawn.

In addition, Cosman has not been found to disclose, in a manner like that claimed, a method of registering an image set for visualizing internal areas of the body including determining a relative position of an imaging device, and an external body part associated with an internal area of the body by providing the external body part with markings, moving the imaging device from an initial position into one or more positions

in which the markings appear in a defined position with respect to each other; and recording the movement of the imaging device and producing an image data set using the imaging device wherein the image data set does not include data on the external body part.

In the above-quoted rejection of claims 1-19, the Examiner points to the following portions of Cosman reproduced below.

FIG. 1 illustrates a neurosurgery setting, showing an object field that includes a patient's head H penetrated by an instrument I, that is, the patient is being operated on through a skull hole 7. As the instrument I, in the form of a probe 1, penetrates the head H, it is desired to know the depth, i.e. the positional relationship of that probe 1 to the head H. The relationship is visualized by combining position data on the probe 1 with data from some imaging means such as CT or MR scanners or angiographic X-rays showing internal views. The interior image data representative of the patient's head may have been previously accumulated and stored in a computer, as described in the referenced U.S. Pat. No. 4,608,977.¹

In FIG. 1, the cameras 4 and 5 are directed at a field including the patient's head H and the probe 1. The orientation and quantification of the camera coordinate data taken from the scan images in the video cameras is registered by index spots 8A, 8B and 8C placed on the patient's head. One alternative to these index spots might be a head ring (disclosed below) which is fixed firmly on to the patient's skull and has index markers on it which may be seen in the views from the cameras 4 and 5. When the index markers are in view of the cameras 4 and 5, the appropriate transformations are made by the processor DP based on the coordinates of the index markers 8A, 8B, and 8C which are known beforehand to the entire data set (CT or MR) of anatomy in the memory M. Thus, the reference points are used to relate objects in the camera fields of view to data for combination with the stored anatomical data.²

In some applications, more than three point markers may be used for redundancy or better definition. As illustrated, the probe 1 in FIG. 1 carries two index markers in the form of light sources 2 and 3, which are visible within a certain range to the cameras 4 and 5. Thus, the orientation of the light sources 2 and 3 relative to the anatomy is sensed by the two cameras 4 and 5 and thus physical position of probe 1 relative to the stored CT or MR data on the head H also is known. Since light sources 2 and 3 are in a predetermined orientation relative to a tip 9 of the probe 1 (defined by object data), the

¹ Col. 4, lines 43-55.

² Col 5, lines 46-62.

actual physical location of the tip 9 relative to the anatomy may be computed in the processor DP.³

It is respectfully submitted that the above-quoted portions of Cosman fail to support the Examiner's anticipation rejection of claims 1-19.

Therefore, the anticipation rejections of amended claims 1 and 19 should be withdrawn because Cosman does not disclose all elements recited in the respective claims.

In rejecting claims 1-19 as being anticipated by Gildenberg, the Office Action provides the following discussion.

Gildenberg discloses a system and method for displaying concurrent video and reconstructed surgical views including a video camera positioned stereotactically to view a surgical opening in a patient and provide data related to stereotactic space. A video camera provides image data, wherein a surgical view image is compared with a reconstructed image from graphics data. The camera is minimally obtrusive so as to allow the surgeon to view the surgical field by naked eye or by microscopic view. The comparable images in a single display are enabled by tracking and correlating the position of the camera to the patient. Thus, by utilization of stereotactic placement or registration of camera positions and patient anatomy, effective dual images (current actual and reference) may be provided in a single display (col 2, lines 35-62). Furthermore, reference image 15 may be from CT, MRI, or other internal imaging systems and can be provided in stereotactic space relative to the heading structure R by localizer means (col 3, lines 62-66). When utilizing the microscope referenced above, the microscope M may be referenced to the patient's head by sequentially focusing it on physical markers 50, 51, 52 borne on the patient's head H. Thus, by registering the microscope M with respect to the patient's head H and tracking it, the resulting data, indicating position and orientation relative to the patient's head, enables the formulation of computer graphics data (col 6, lines 35-41).

Like the above-discussed anticipation rejection based on Cosman, it is unclear how the Examiner is applying Gildenberg to each of the 19 claims purportedly anticipated by Gildenberg in that many of the elements recited in claim 1 and claim 3

³ Col. 5, line 63 - col. 6, line 7.

(and various other dependent claims) are not addressed in the rejection. For at least this reason, the rejection should be withdrawn.

In addition, Gildenberg is not understood to disclose the claimed method including determining relative position of an imaging device and an external body part is determined, in part, by providing the external body part with markings and moving the imaging device from an initial position into one or more positions where the markings appear in a defined position with respect to each other.

Gildenberg's deficiencies with respect to amended claim 1 are due, in part, to the fact that Gildenberg is concerned with a different type of system and method from that recited in the pending claims. Gildenberg is understood to disclose a system in which a video camera is positioned stereotactically to view a surgical opening such that an image from the video camera may be displayed side-by-side or overlapped with a reference image.

If the Examiner is construing Gildenberg's cameras 42, 43 & 44 as the claimed imaging device, then Gildenberg is deficient because these cameras are not used to produce an image data set for the internal area of the body, wherein the image data set does not include data on the external body part, as is recited in the pending claims. Alternatively, if the Examiner is construing microscope M as the claimed imaging device, then Gildenberg is deficient because microscope M is not moved from an initial position into one or more positions in which the markings appear in a defined position with respect to each other, as is recited in the pending claims.

Therefore, the anticipation rejections of amended claims 1 and 19 should be withdrawn because Gildenberg does not disclose all elements recited in the respective claims.

The dependent claims, while reciting additional features, are not being independently discussed in as much as they are allowable for at least the same reasons as the independent claims from which they depend. This absence of a comment regarding the dependent claims, however, should not be construed as an acquiescence to the contentions made in the Office Action.

Telephone Interview

If it is determined that the application is not in condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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